

CLAIMS

1. A method of treatment of a patient undergoing opioid analgesic therapy which comprises minimising or mitigating the side effects of the opioid by the administration of a therapeutically effective amount of devazepide.
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2. A method of treatment of a patient requiring analgesia which comprises the administration of a therapeutically effective amount of an opioid analgesic whilst minimising the side effects of the opioid by the separate, simultaneous or sequential
10 administration of a therapeutically effective amount of devazepide.
3. A method according to claim 1 characterised in that the opioid is selected from the group morphine, or a salt thereof such as the sulphate, chloride or hydrochloride, or the other 1,4-hydroxymorphinan opioid analgesics such as naloxone, meperidine, butorphanol or pentazocine, or morphine-6-glucuronide, codeine, dihydrocodeine, diamorphine, dextropropoxyphene, pethidine, fentanyl, alfentanil, alphaprodine, buprenorphine, dextromoramide, diphenoxylate, dipipanone, heroin (diacetylmorphine), hydrocodone (dihydrocodeinone), hydromorphone (dihydromorphinone), levorphanol, meptazinol, methadone, metopon (methyldihydromorphinone), nalbuphine, oxycodone
15 20 (dihydrohydroxycodeinone), oxymorphone (dihydrohydroxymorphinone), phenadoxone, phenazocine, remifentanil, tramadol, or a salt of any of these.
4. A method according to claim 2 characterised in that the opioid is selected from the group morphine, or a salt thereof such as the sulphate, chloride or hydrochloride, or the other 1,4-hydroxymorphinan opioid analgesics such as naloxone, meperidine, butorphanol or pentazocine, or morphine-6-glucuronide, codeine, dihydrocodeine, diamorphine, dextropropoxyphene, pethidine, fentanyl, alfentanil, alphaprodine, buprenorphine, dextromoramide, diphenoxylate, dipipanone, heroin (diacetylmorphine), hydrocodone (dihydrocodeinone), hydromorphone (dihydromorphinone), levorphanol,
25 30 meptazinol, methadone, metopon (methyldihydromorphinone), nalbuphine, oxycodone

(dihydrohydroxycodeinone), oxymorphone (dihydrohydroxymorphinone), phenadoxone, phenazocine, remifentanil, tramadol, or a salt of any of these

5. A method according to claim 3 characterised in that the opioid is selected from
the group hydromorphone, oxycodone, morphine and fentanyl.

6. A method according to claim 4 characterised in that the opioid is selected from
the group hydromorphone, oxycodone, morphine and fentanyl.

10 7. A method according to claim 5 characterised in that the opioid is selected from
the group morphine and morphine sulphate.

8. A method according to claim 6 characterised in that the opioid is selected from
the group morphine and morphine sulphate.

15 9. A method according to claim 1 characterised in that the method of delivery of the
devazepide and/or the opioid is selected from the group, administration intravenously,
orally, intrathecally, intranasally, intrarectally, intramuscularly/subcutaneously, by
inhalation and by transdermal patch.

20 10. A method according to claim 2 characterised in that the method of delivery of the
devazepide and/or the opioid is selected from the group, administration intravenously,
orally, intrathecally, intranasally, intrarectally, intramuscularly/subcutaneously, by
inhalation and by transdermal patch.

25 11. A method according to claim 9 characterised in that the devazepide is
administered intravenously or orally.

30 12. A method according to claim 10 characterised in that the devazepide is
administered intravenously or orally.

13. A method according to claim 11 characterised in that the devazepide is administered orally.
- 5 14. A method according to claim 12 characterised in that the devazepide is administered orally.
- 10 15. A method according to claim 9 characterised in that the opioid is administered intravenously and the devazepide is administered intravenously.
16. A method according to claim 10 characterised in that the opioid is administered intravenously and the devazepide is administered intravenously.
- 15 17. A method according to claim 9 characterised in that the opioid is administered orally and the devazepide is administered orally.
18. A method according to claim 10 characterised in that the opioid is administered orally and the devazepide is administered orally.
- 20 19. A method according to claim 9 characterised in that the opioid is administered by intravenous administration or oral administration.
20. A method according to claim 10 characterised in that the opioid is administered by intravenous administration or oral administration.
- 25 21. A method according to claim 1 characterised in that the daily dosage of devazepide is up to 0.7 mg/kg/day.
22. A method according to claim 2 characterised in that the daily dosage of devazepide is up to 0.7 mg/kg/day.

23. A method according to claims 21 characterised in that the daily dosage of devazepide is from 25 µg/kg/day to 0.7 mg/kg/day.

5 24. A method according to claims 22 characterised in that the daily dosage of devazepide is from 25 µg/kg/day to 0.7 mg/kg/day.

25. A method according to claim 23 characterised in that the daily dosage of devazepide is from 50 µg/kg/day to 0.5 mg/kg/day.

10 26. A method according to claim 24 characterised in that the daily dosage of devazepide is from 50 µg/kg/day to 0.5 mg/kg/day.

15 27. A method according to claim 25 characterised in that the devazepide is administered orally and the daily dosage of devazepide is from 0.07 mg/kg/day to 0.29 mg/kg/day.

20 28. A method according to claim 26 characterised in that the devazepide is administered orally and the daily dosage of devazepide is from 0.07 mg/kg/day to 0.29 mg/kg/day.

25 29. A method according to either of claims 25 characterised in that the devazepide is administered intravenously administration the dosage of devazepide is from 50 µg/kg/day to 0.5 mg/kg/day.

30. A method according to either of claims 26 characterised in that the devazepide is administered intravenously administration the dosage of devazepide is from 50 µg/kg/day to 0.5 mg/kg/day.

31. A method according to claim 1 characterised in that the daily dosage of the opioid is from 5 to 2000mg daily.

32. A method according to claim 2 characterised in that the daily dosage of the
5 opioid is from 5 to 2000mg daily.

33. A method according to claim 31 characterised in that the daily dosage of the opioid is from 5 to 100mg daily.

10 34. A method according to claim 32 characterised in that the daily dosage of the opioid is from 5 to 100mg daily.

15 35. A method according to claim 1 characterised in that the side effect which is inhibited, mitigated or minimised is selected from the group, constipation, dizziness, tiredness/fatigue and vomiting.

36. A method according to claim 2 characterised in that the side effect which is inhibited, mitigated or minimised is selected from the group, constipation, dizziness, tiredness/fatigue and vomiting.

20 37. A method according to claim 1 characterised in that the devazepide used is the S enantiomer wherein the level of R enantiomer is not greater than 1.5% w/w.

25 38. A method according to claim 2 characterised in that the devazepide used is the S enantiomer wherein the level of R enantiomer is not greater than 1.5% w/w.

39. The use of devazepide in the manufacture of a medicament which inhibits or mitigates the undesirable side effects of administration of a therapeutically effective amount of an opioid analgesic.

40. The use according to claim 39 characterised in that the devazepide used is the S enantiomer wherein the level of R enantiomer is not greater than 1.5% w/w.

5 41. The use of devazepide in the manufacture of a medicament for use in the method of either of claim 1.

42. The use of devazepide in the manufacture of a medicament for use in the method of either of claim 2.

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